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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,367	12/09/1998	ULF SCHRODER	REF/SCH29644	1613

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No.	Applicant(s)	
	09/147,367	SCHRODER, ULF	
	Examiner	Art Unit	
	Gollamudi S Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *92-141* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92-141* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The filing of the RCE and amendment dated 6-01-04 are acknowledged.

Claims included in the prosecution are 92-141.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 92-141 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant introduces the term 'emulsion' in the independent claims and point out to page 6, lines 31-32 for support. Applicant on page 6, lines 27-32 state the following:

> "Another systems that to some extent are similar to the present invention are formulations based on diglycerides. However, these systems are scientifically defined as emulsions of triglycerides where surfactants are used for stabilization. As stabilizers phospholipids or any other type of amphiphilic molecules such as Tween@ are normally used. Furthermore, the appearance of such emulsions are normally milky, indicating a size

of the oil droplets of about 1 micro meter".

It is clear from this statement that applicant is referring to the prior art and not instant invention. Thus, the term, 'emulsion' is has no support in the specification as originally filed and therefore, deemed to be new matter.

3. Claims 92-141 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nasal administration of Diphtheria toxoid or influenza or rota virus antigens in micellar compositions containing monoolein and oleic acid, does not reasonably provide enablement for generic monoglycerides and fatty acid of 6-24 carbon atoms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Instant claims are drawn to generic monoglyceride wherein the fatty acids have 6-24 carbon atom; this virtually includes many fatty acids both saturated and unsaturated; similar is the case with fatty acids with 6-24 carbon atoms. A careful evaluation of the specification indicates that only a combination of monoolein and oleic acids are used and the results obtained as evident from the specification mixed in terms of the claimed effect on specific viruses and bacteria tested compared to art known adjuvant, alum'. Based on these mixed results applicant extrapolates to generic 'antigen' and generic 'administration' and generic 'monoglycerides' and 'fatty acids'. Furthermore, the experiments shown in the specification indicates that the adjuvant is administered together with the bacterial or viral antigen and not separately. Applicant's own experiments

indicates unpredictability and therefore, it would require undue experimentation by one of ordinary skill in the art to determine which combinations of monoglycerides and fatty acids would be effective against which virus or bacteria or parasites or cancer antigens. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to specific mode of administration of compositions containing specific monoglyceride and fatty acid for eliciting the immune response to specific organisms.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 92-141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While the preamble in claims 92 and 93 recites 'antigen', the method part recited subsequently recites no antigen in the composition and thus, inconsistent with the preamble.

According to claims 92 and 93, the amount is 'immune responsive enhancing effective amounts'. The dependent claims 105 and 125 however, recite the amounts in gram quantities. Is the amount in these claims effective amount? These dependent claims are confusing.

According to claims 92 and 93, the composition is an emulsion, meaning that there is an aqueous medium; claims 104 and 128 which recite 'composition

further comprises an aqueous medium' thus, is inconsistent with the parent claims.

The independent claims 92 and 93 recite 'consisting essentially of' with respect to the adjuvant. While it is understandable that the addition of other materials such as pH controlling agents does not change the novel nature of the composition, an addition of another adjuvant certainly does change the novel nature of the composition. Claims 105, 107, 129 and 131 are inconstant with the parent claims.

"Diphtheria' is misspelt in claims 111 and 135.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 65-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/06921 by itself in combination with Amselem (5,716,637), Wright (5,730,989), Koga (5,352,450), Carrano (5,739,118) individually or in combination.

As pointed out before, WO discloses formulations containing monoglyceride preparation. The preparation contained 98.8% monoglycerides and 1 % free fatty acids. The composition is for the delivery of vaccines (note

page 20, lines 25-30, pages 45-47 and claims). What is lacking in WO is the presence of fatty acid in 2 % (instant ratio of monoglyceride to fatty acid is 50:1, claim 92) or in 10 % (claim 93). It would have been obvious to one of ordinary skill in the art to vary the amounts of fatty acid in WO to obtain the best possible results. WO also lacks the teachings of specific pathogen such as influenza or rotavirus recited in instant claims. However, since WO teaches the general applicability of the composition for the delivery of vaccines, it would have been obvious to one of ordinary skill in the art to use the adjuvant taught by WO to any antigen with a reasonable expectation of success.

Amselem teaches oleic acid as one of the components for the delivery of vaccine formulations (note the examples).

Wright while teaching oral vaccine formulations teaches oleic acid as one of the components (note col. 4, lines 11-22).

Koga similarly teaches oleic acid as one of the components in vaccine formulations for preventing dental caries (col. 20, line 59 et seq.).

Carrano teaches oleic acid is a preferred as a genetic vaccine facilitator (col. 14, lines 6-51).

It would have been obvious to one of ordinary skill in the art to add oleic acid in the formulations of WO with the expectation of obtaining at least an additive effect or the best possible results since the references Amselem, Wright, Koga and Carrano each teach that oleic acid is used in vaccine preparations as an adjuvant.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the claims are now amended to recite 'emulsion' form of the composition and that WO's composition is not an emulsion. This argument is not found to be persuasive for the following reasons. First of all, the reference teaches the same components, that is, a monoglyceride and a fatty acid and in amounts which are similar to instant amounts and the compositions in both instant invention and WO are sonicated (see Examples 1-3 on page 8 of instant specification and page 20, line 25 through page 21, line 25; page 31, line 31) and therefore, one would expect the formulations in both to be the same although applicant calls it an emulsion. Applicant provides no specific arguments with regard to the secondary references. The examiner has already addressed prior applicant's arguments pertaining to these references.

3. Claims 65-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/06921 by itself in combination with Amselem (5,716,637), Wright (5,730,989), Koga (5,352,450), Carrano (5,739,118) individually or in combination as set forth above, further in view of Isaacs (4,997,851) cited before.

The teachings of WO, Amselem, Koga, Wright and Carrano have been discussed above. As discussed before, Isaacs teaches the effectiveness of the combination of a monoglyceride and a fatty acid in killing viruses and bacteria (abstract, Tables and claims).

One of ordinary skill in the art would be further motivated to add a fatty acid to the formulations of WO since fatty acids are also effective in killing the viruses and bacteria as taught by Isaacs.

Applicant provides no specific arguments with regard to Isaacs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM-4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G S Kishore

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